

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND  
COMPOUNDING PHARMACY, INC.  
PRODUCTS LIABILITY LITIGATION**

**Master Docket No. 1:13-md-2419-FDS**

**CONSTANCE GAY RHODES,**  
**Plaintiff,**

**v.**

**NEW ENGLAND COMPOUNDING  
PHARMACY, INC. d/b/a NEW  
ENGLAND COMPOUNDING CENTER,**

**This Document Relates To:  
Civil Action No. 1:13-cv-10504-FDS**

**and**

**CARILION SURGERY CENTER  
NEW RIVER VALLEY LLC, D/B/A  
NEW RIVER VALLEY SURGERY  
CENTER, LLC,**

**Defendants.**

**MEMORANDUM IN SUPPORT OF MOTION TO DISMISS FOR  
FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED**

COMES NOW Defendant Carilion Surgery Center New River Valley, LLC, d/b/a New River Valley Surgery Center, LLC (“New River”), by counsel, and for its Memorandum in Support of Motion to Dismiss Plaintiff’s Complaint, states:

**FACTS**

Plaintiff claims that she visited New River in Christiansburg, VA, and received multiple injections of methylprednisolone acetate to treat her spinal pain. (Compl. ¶ 20.) Plaintiff alleges that the injections she received contained a fungus that can cause fungal meningitis. (*Id.* ¶ 20.) According to Plaintiff’s Complaint, the methylprednisolone acetate was manufactured by the

New England Compounding Pharmacy, Inc d/b/a New England Compounding Center (“NECC”)—also a named defendant in this suit. (*Id.* ¶ 14.) Plaintiff asserts that after receiving the injection, she began experiencing symptoms consistent with fungal meningitis and has sought medical treatment to address those symptoms. (*Id.* ¶¶ 21–25.) Based on these facts, Plaintiff has filed suit against New River and NECC, asserting claims for design and manufacturing defect, breach of express and implied warranties and negligence.

### **STANDARD OF REVIEW**

To survive a motion to dismiss under Fed.R.Civ.P. 12(b)(6), a complaint must allege “a plausible entitlement to relief.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). “While a complaint attacked by a Rule 12(b)(6) motion does not need detailed factual allegations, a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of a cause of action’s elements will not do.” *Id.* at 545, 127 S.Ct. 1955 (internal citations omitted). *See also Berner v. Delahanty*, 129 F.3d 20, 25 (1st Cir.1997) (dismissal for failure to state a claim is appropriate if the pleadings fail to set forth “factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory”), quoting *Gooley v. Mobil Oil Corp.*, 851 F.2d 513, 515 (1st Cir.1988). “If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal.” *SEC v. Tambone*, 597 F.3d 436, 442 (1st Cir.2010), citing *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955.

*Kelly v. Deutsche Bank Nat. Trust Co.*, 789 F. Supp. 2d 262, 265 (D. Mass. 2011)

### **ARGUMENT**

#### **I. New River is a service provider, not a seller, and therefore not subject to products liability claims for treatment rendered.**

In her Complaint, Plaintiff characterizes New River as a distributor of “pain management products and devices to its clients.” (Compl. ¶ 4.) Yet Plaintiff also states that she visited New River’s offices to receive medical treatment, specifically the epidural injection of the

methylprednisolone acetate. (Compl. ¶ 20.) Thus, while Plaintiff's Complaint does allege that "Defendants" sold her the allegedly-tainted steroid (Compl. ¶ 8), it also alleges that New River provided her with the service of medical treatment. (Compl. ¶¶ 8, 20.)

Yet Virginia law is clear that if an entity purely is a service provider, it cannot also be a seller with regards to a products liability action. A "threshold question" when determining whether a warranty action can lie "is whether the transaction was one for the sale of goods or the provision of services." *AAF-McQuay, Inc. v. MJC, Inc.*, 2002 WL 172442, \*3 (W.D.Va. 2002). The Uniform Commercial Code ("U.C.C."), as adopted by Virginia, applies to transactions in goods, not services. Va. Code. § 8.2-102. In order to establish warranty claims against New River, Plaintiff must be able to show that New River is a seller of goods under the U.C.C. *See* Va. Code §§ 8.2-313–15 (setting forth the requirements for establishing express and implied warranties). If the defendant "is a professional providing services . . . the law of warranty does not apply." *Gressman v. Peoples Service Drug Stores, Inc.*, 10 Va. Cir. 397 (Richmond Cir. Ct. Feb. 9, 1988) (citing *Vann v. Harden*, 188 Va. 555, 565, 47 S.E.2d 314 (1948); *Gagne v. Bertran*, 43 Cal.2d 481, 487, 275 P.2d 15 (1954); *J. O. Morry Stores v. Skoog Constr. Co.*, 38 Ill.App.3d 747, 348 N.E.2d 474 (1976)). "Whether the U.C.C. applies turns on a question as to whether the contract . . . involved principally a sale of goods, on the one hand, or a provision of services, on the other." *Coakley v. Williams*, 706 F.2d 456, 459 (4th Cir. 1983). "Thus, before applying the U.C.C., courts generally examine the transaction to determine whether the sale of goods predominates." *Princes Cruises, Inc. v. General Elec. Co.*, 143 F.3d 828, 832 (4th Cir. 1998).

New River is engaged in the business of providing medical services, not the business of selling methylprednisolone acetate. New River provides patients with surgical services and only

administers medicine as a part of the overall treatment service. Courts in Virginia and across the United States have held that entities involved in the provision of medical treatment provide their patients with services and are not “sellers” or “merchants” under the U.C.C.

Even in situations where a defendant does, in fact, sell drugs directly to the purchaser, where it occurs in the context of medical treatment Virginia courts have held that an action in warranty cannot be sustained. In *Gressman v. Peoples Service Drug Stores, Inc.*, 10 Va. Cir. 397 (Richmond Cir. Ct. Feb. 9, 1988), the plaintiff visited the defendant pharmacy to have a prescription for chlorpromazine filled. *Id.* at \*1. The pharmacy mistakenly filled plaintiff’s prescription with chlorpropamide, not chlorpromazine. *Id.* Plaintiff subsequently ingested the incorrect medication, which caused her severe injuries, brain damage and “rendered her semi-comatose.” *Id.* Plaintiff, through her Guardian, sued the defendant pharmacy in a products liability action, asserting claims for breaches of express warranty and implied warranties of merchantability and fitness for a particular purpose. *Id.*

Defendant demurred to the warranty claims, arguing that “a pharmacist is not a merchant selling goods, but is a professional providing services” and therefore the warranty claims could not lie. *Id.* at \*6. The Court looked to the Virginia Code (the “Code”) for guidance on whether to classify the pharmacy as a seller or service provider. The Code defined the “practice of pharmacy” as a “health service” “concerned with the art and science of” preparing and dispensing “drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease . . . .” Va. Code. § 54-524.2. In addition, the Code defined “health care” as

[A]ny act, or treatment performed or furnished, or which should have been performed or furnished, by any health care provider for, to, or on behalf of a patient during the patient’s medical diagnosis, care, treatment or confinement.

Va. Code § 8.01-581.1. The Court observed that, by reading the two Code provisions together, the defendant pharmacy was engaged in providing health care:

Since a pharmacist is unquestionably a “health care provider,” and since the delivery of a prescription drug is unquestionably and “act,” the delivery of a prescription drug to a patient by a pharmacist is unquestionably “health care.”

*Gressman*, 10 Va. Cir. 397, at \*8. The Court reasoned further that the pharmacist’s actions of preparing prescriptions are not “simply for their own edification,” but are instead undertaken “in order to dispense.” *Id.* Because the “sale of a prescription drug by a pharmacist is necessarily ‘health care . . . it is not a ‘sale’ within the meaning of the Uniform Commercial Code, and the court so holds.’” *Id.* The Court accordingly sustained the defendant’s demurrer to plaintiff’s warranty claims. *Id.*

In *Coffman v. Arthrex, Inc.*, 69 Va. Cir. 17 (August Co. Cir. Ct. March 31, 2005), plaintiff was admitted to the Augusta Medical Center for surgery to repair a torn rotator cuff. *Id.* at \*1. During the procedure, a biodegradable screw was inserted into plaintiff’s shoulder. *Id.* The screw was manufactured and sold to the defendant medical center by co-defendant Arthrex, Inc. *Id.* Subsequent to plaintiff’s surgery, the screw failed, thereby necessitating additional surgical procedures. *Id.*

Plaintiff sued the defendant medical center and product manufacturer on breach of warranty theories. *Id.* The defendant medical center demurred to plaintiff’s warranty claims, arguing that it was a service provider, not a seller or merchant of goods. *Id.* \*2. In a brief opinion, the Court sustained the demurrer. “The Court is of the opinion that health care providers render a service to their patients, and the transfer of any type of good or device to the patient during treatment is merely incidental to that treatment.” *Id.* The Court reasoned that “had the General Assembly intended health care providers to be treated as “merchants,” such a

provision would have been covered in the Medical Malpractice Act. It clearly is not.” *Id.* The Court concluded, “[t]he health care provider is not a ‘seller’ and is not subject to liability on a products liability theory.” *Id.*

Though the Supreme Court of Virginia has not examined a case that is directly on point, their reasoning in *Commonwealth of Virginia Dept. of Taxation v. Bluefield Sanitarium, Inc.*, 216 Va. 686, 222 S.E.2d 526 (1976), a tax case, is instructive. There, the Supreme Court of Virginia had to determine whether a private hospital was exempt from sales tax on the hospital’s bulk purchase of drugs from the drug manufacturers and wholesalers. *Id.* at 687, 222 S.E.2d at 527. The drug at issue was one that the hospital dispensed to its patients. *Id.* The Court ruled that the Hospital was a consumer of the drug, not a retailer, and therefore was not exempt from the tax at issue. *Id.* at 689, 222 S.E.2d at 528.

In so ruling, the Supreme Court of Virginia made important observations that are relevant to the case at bar. The Court noted that “[a] hospital is engaged primarily in rendering services, and the meals, drugs, bandages, etc. provided to its patients are incidental to the rendition of these services.” *Id.* at 688, 222 S.E.2d at 528. The Court also remarked that “[n]o taxable event occurs with respect to drugs supplied by the hospital to the patient, for such drugs are being supplied and administered in the performance of its service as a hospital.” *Id.* at 689, 222 S.E.2d at 528. “Irrespective of whether the hospital is providing beds, food or medicines, the hospital is the ‘consumer’ in the tax sense because all property acquired by it is for use in the performance of its service to patients.” *Id.* Thus, in *Bluefield Sanitarium* the Supreme Court of Virginia directly examined whether a health care provider was a service provider or a seller of goods and held that the “service provider” classification was correct. Applying such logic to this case

compels the conclusion that New River is likewise a service provider and therefore not subject to products liability claims.

Other jurisdictions are in agreement with Virginia that health care providers render services and cannot be subjected to products liability claims based on the administration of medicine incidental to the service rendered. In *Royer v. Catholic Medical Center*, 144 N.H. 330, 741 A.2d 74 (1999), the Supreme Court of New Hampshire was confronted with a plaintiff's product liability claims against a hospital arising from a defective prosthetic knee. *Id.* at 331, 741 A.2d at 75. The defendant moved to dismiss, arguing that it was not a "seller of goods" and therefore not subject to the product liability claims. *Id.* The Court noted at the outset that "[i]f the defendant merely provides a service, however, there is no liability absent proof of a violation of a legal duty." *Id.* at 332, 741 A.2d at 76.

The Court then reviewed the law of other jurisdictions and observed that "[a] majority of the jurisdictions" that have addressed the issue have dismissed products liability claims against health care providers, "similarly reasoning that the health care provider primarily renders a service, and that the provision of a prosthetic device is merely incidental to that service." *Id.* at 333, 741 A.2d at 76–77 (citing *Cafazzo v. Cent. Medical Health Services*, 542 Pa. 526, 668 A.2d 521, 524–25 (1995); *In re Breast Implant Product Liability*, 331 S.C. 540, 503 S.E.2d 445, 448–51 (1998); Annotation, *Liability of Hospital or Medical Practitioner under Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drug, Medical Instrument, or Similar Device used in Treating Patient*, 65 A.L.R. 5th 357, 387-96 (1999) (collecting cases).

The Court then framed the issue as "not whether the defendant 'sold' or transferred a prosthetic knee, but whether the defendant was an entity 'engaged in the business of selling' prosthetic knees so as to warrant the imposition of liability without proof of legal fault." *Id.* at

333, 741 A.2d at 77. “The thrust of the inquiry is thus not on whether a separate consideration is charged for the physical material used in the exercise of medical skill, but what service is performed to restore or maintain the patient’s health.” *Id.* at 334, 741 A.2d at 77 (quoting *Cafazzo v. Cent. Medical Health Servs.*, 542 Pa. 526, 529, 668 A.2d 521, 524 (1995)). The Court then reasoned that “it is evident that [plaintiff] entered [the hospital] not to purchase a prosthesis, but to obtain health care services that included the implantation of the knee, with the overall objective of restoring his health.” *Id.* at 334, 741 A.2d at 78.

Public policy implications were also central to the Court’s ruling in *Royer*. “Because ‘ordinarily there is no possibility that a distributor other than the manufacturer created a design defect[,] . . . strict liability would impose liability when there is no possibility of negligence.’” *Id.* at 335, 741 A.2d at 78 (quoting *Parker v. St. Vincent Hosp.*, 122 N.M. 39, 919 P.2d 1104, 1108–09 (2009)). “Further, holding health care providers strictly liable for defects in prosthetic devices necessary to the provision of health care would likely result in higher health care costs borne ultimately by all patients[.]” *Id.* (citing *Ayyash v. Henry Ford Health Systems*, 210 Mich.App. 142, 533 N.W.2d 353, 355 (1995); *Parker*, 919 P.2d at 1108; *Cafazzo*, 668 A.2d at 527). This imposition of liability would “‘place an unrealistic burden on the physicians and hospitals of this state to test or guarantee the tens of thousands of products used in hospitals by doctors.’” *Id.* (citing *Ayyash*, 522 N.W.2d at 356; *Parker*, 919 P.2d at 1110). Additionally, “research and innovation in medical equipment and treatment would be inhibited” if products liability actions could be maintained against the service provider. *Id.* (citing *Cafazzo*, 668 A.2d at 527; *Hoff v. Zimmer, Inc.*, 746 F.Supp. 872, 874–75 (1990)). The Court concluded that the “peculiar characteristics of medical services . . . outweigh any reasons that might support the imposition of strict liability in this context.” *Id.*



This Court should follow the majority rule as applied in Virginia precedent and in persuasive authority from across the United States. The injection Plaintiff received was a *medical service*, and even if the Court agreed with the Plaintiff that New River sold the injection to Plaintiff, such sale was merely ancillary to the service New River provided. It was even further removed from the context of a “sale of a product” than was the situation in the *Gressman* case discussed above. There, the Court held that even in that more direct transactional context the fact that the transfer of the drug to the Plaintiff occurred in the provision of medical services rendered the Plaintiff’s warranty claim deficient. New River is not a “seller” or “merchant” subject to products liability warranty claims. This Court should, in accordance with Virginia precedent and the majority rule of other jurisdictions, dismiss Plaintiff’s warranty claims against New River for failure to state a claim upon which relief could be granted.

## **II. Plaintiff failed to comply with the provisions of Virginia’s Medical Malpractice Act.**

Virginia’s Medical Malpractice Act (the “Act”) provides for certain procedures associated with claims brought against health care providers. Virginia Code § 8.01-20.1 requires that plaintiffs, for any medical malpractice action, certify that an expert has reviewed their claims and provided a written opinion that the defendant deviated from the standard of care. Va. Code. § 8.01-20.1. Virginia Code § 8.01-581.1 defines malpractice as “any *tort action or breach of contract action* for personal injuries or wrongful death, based on health care for professional services rendered, or which should have been rendered, by a health care provider, to a patient.” Va. Code. § 8.01-581.1 (emphasis added). As described in Plaintiff’s Complaint, IGPM renders health care services and qualifies as a health care provider under the Act. *See* Va. Code § 8.01-581.1 (defining “Health care provider” and “health care”). Plaintiff’s claim of negligence is clearly a “tort action . . . for personal injuries . . . based on health care for professional services

rendered . . . by a health care provider, to a patient.” Plaintiff’s negligence claim is devoid of the required certification and therefore must be dismissed as deficient under the Code of Virginia.

Claims for breach of express or implied warranties sound in contract. *See, e.g., Burner v. Ford Motor Co.*, 52 Va. Cir. 301 (Prince William Co. Cir. Ct. June 7, 2000) (noting that plaintiff’s breach of implied warranty claims were “contractual” and implicated the statute of limitations period applicable to contracts). Malpractice is defined to include “breach of contract actions.” Va. Code 8.01-581.1. IGPM is a health care provider subject to the requirements of the Act. Va. Code § 8.01-581.1. As discussed above, the act sets forth pre-suit certification requirements for any malpractice action against health care providers. Va. Code § 8.01-20.1. Plaintiff’s warranty claims are devoid of any certification that an expert reviewed plaintiff’s claims and provided the requisite written opinion. Consequently, Plaintiff’s warranty claims are deficient under the Code and must be dismissed.

### **III. Under Virginia law, health care providers are not responsible for the compounding of medicine.**

Under Virginia law, pharmacists, not health care providers, are responsible for supervising the compounding process, “which shall include a final check for accuracy and conformity to the formula of the product . . . appropriate conditions and procedures, and appearance of the final product.” Va. Code § 54.1-3410.2(D). Additionally, it is the pharmacist’s responsibility, not the responsibility of the treating health care provider, to “ensure compliance with USP-NF standards for . . . sterile . . . compounding.” Va. Code § 54.1-3410.2(E).

The Complaint is clear that the source of Plaintiff’s alleged injuries were the alleged defects in the methylprednisolone acetate that Plaintiff received via injection. Therefore, under the Code, there are no facts set forth in the Complaint which could implicate liability on behalf

of any health care provider, including New River. Under the facts set forth in the Complaint, Plaintiff visited New River for treatment and New River injected Plaintiff with a drug which New River received after that drug was supposed to have undergone the appropriate tests for purity and safety.

New River's physicians must be able to rely on the statutory scheme which obligates those who provide drugs to New River to ensure those drugs are safe. Any other scheme would result in an unduly burdensome set of requirements whereby New River and other health care providers would have to independently test all drugs they administer. Such a requirement would cripple the administration of medicine and undermine the effective treatment of patients. As the Supreme Court of New Hampshire observed in *Royer v. Catholic Medical Center*, "holding health care providers strictly liable for defects in [medical goods] necessary to the provision of health care would likely result in higher health care costs borne ultimately by all patients[;] . . . place an unrealistic burden on the physicians and hospitals" and inhibit "research and innovation in medical equipment and treatment." *Royer*, 144 N.H. at 335, 741 A.2d at 78 (internal citations omitted). This Court should not impose liability against New River for responsibilities that the Virginia legislature has vested elsewhere.

**IV. Even if the U.C.C. applied to New River, Plaintiff fails to allege sufficient facts to support a claim for breach of express warranty or implied warranty of fitness for a particular purpose.**

Virginia Code § 8.2-313 provides the requirements for creating express warranties under the U.C.C:

(1) Express warranties by the seller are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

(2) It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

Va. Code § 8.2-313. In the present matter, Plaintiff only states that New River “expressly warranted that the methylprednisolone acetate was safe and effective” (Compl. ¶ 48.) Such allegations are wholly insufficient to establish an “affirmation of fact or promise” or any other basis for an express warranty. In *Sanders v. Medtronic, Inc.*, 2006 WL 1788975; 60 U.C.C. Rep.Serv.2d 342 (E.D.Va. 2006), plaintiff asserted a claim for breach of express warranty based on the sale of a medical product. *Id.* at \*27. In that case, the plaintiff supported her allegations with more specific charges than what Plaintiff has asserted in the case at bar:

Plaintiff alleges in her Motion for Judgment that the defendants provided documentation to the plaintiff that stated the following: ‘The battery life of the pulse generator depends on the number of hours you use it each day and how strong the stimulation must be to control your pain. Your doctor can give you an estimate once your pulse generator settings have been determined.’

*Id.* The complaint alleged that the implanting surgeon gave an estimate of four to five years of battery life. The Court analyzed the plaintiff’s assertions and concluded that they failed to state a claim. “The problem with plaintiff’s breach of express warranty claim . . . is that the plaintiff has not alleged any facts that suggest that [defendant] made any express warranties to the plaintiff

regarding the . . . devices.” *Id.* If the allegations in *Sanders* were inadequate, then the lesser allegations in this case cannot support a breach of express warranty claim.

Nor does Plaintiff adequately state a claim for breach of warranty of fitness for a particular purpose. Indeed, it is far from clear if Plaintiff even makes such a claim. Plaintiff simply states that New River “knew the use for which the methylprednisolone acetate was intended, and impliedly warranted the methylprednisolone acetate would be of merchantable quality and safe for such use.” (Compl. ¶ 53.) To the extent that this allegation constitutes a claim for breach of warranty of fitness for a particular purpose, the claim is insufficient. Mere allegations of the ordinary purpose for which goods are used are insufficient to establish a particular purpose. The Official Comment to Va. Code § 8.2-315 states, “[a] particular purpose differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question.” Va. Code § 8.2-315 cmt. 2. Allegations of ordinary purpose are insufficient to set forth a particular purpose. *Id.*; *Sanders*, 2006 WL 1788975; 60 U.C.C. Rep.Serv.2d 342 (E.D.Va. 2006). Plaintiff’s Complaint in this matter is devoid of any allegations of a *particular* purpose. Consequently, the claim for breach of implied warranty of fitness for a particular purpose should be denied.

### **CONCLUSION**

WHEREFORE, Defendant Carilion Surgery Center New River Valley, LLC, d/b/a New River Valley Surgery Center, LLC, respectfully moves this Court to grant its Motion to Dismiss, to enter final judgment in its favor, to dismiss this action against it from the Court’s docket, to award it the costs and attorneys’ fees associated with the defense of this action, and for such

other and further relief as the needs of this case may require and which this Court deems appropriate.

Respectfully submitted,

CARILION SURGERY CENTER  
NEW RIVER VALLEY LLC, D/B/A  
NEW RIVER VALLEY SURGERY  
CENTER, LLC

By: /s/ Michael P. Gardner  
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 11th day of June 2013, a true and exact copy of the foregoing was filed with the Clerk of the Court using the CM/ECF filing system, thereby providing electronic notice to jtravers@millerfirmllc.com, mmiller@millerfirmllc.com, and will@moodyrrlaw.com, counsel for plaintiff, and to rebecca.herbig@bowmanandbrooke.com, counsel for defendant NECC. Paper copies will be sent to those indicated as non registered participants on June 11, 2013.

/s/ Michael P. Gardner